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| APPLICATION NO.                                    | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|--|---------------|----------------------|--------------------------|------------------|
| 10/624,289   | 07/21/2003    | Pier F. Cirillo      | 9/158-161-4-D3           | 7392             |
| 28509 759  | 90 03/24/2005 |                      | EXAMINER                 |                  |
| MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION |               |                      | DAVIS, ZINNA NORTHINGTON |                  |
| 900 RIDGEBURY ROAD                                 |               |                      | ART UNIT                 | PAPER NUMBER     |
| P O BOX 368  |               |                      | 1625                     |                  |
| RIDGEFIELD, CT 06877-0368                          |               |                      | DATE MAILED: 03/24/2005  |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Application No.         | Applicant(s)   |  |  |  |  |
|---|---|-------------------------|--|--|--|--|--|
| Office Action Summary   |   | 10/624,289              | CIRILLO ET AL.                                       |  |  |  |  |
|   |   | Examiner                | Art Unit   |  |  |  |  |
|   |   | Zinna Northington Davis | 1625   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply   |   |                         |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |   |                         |  |  |  |  |  |
| 1)🖂   | _   |                         |  |  |  |  |  |
| 2a)□  | · · · · · · · · · · · · · · · · · · ·   | is action is non-final. |  |  |  |  |  |
| 3)  | <u> </u>  |                         |  |  |  |  |  |
| Disposition of Claims   |   |                         |  |  |  |  |  |
| 4)⊠   | 4)⊠ Claim(s) <u>1-22</u> is/are pending in the application.   |                         |  |  |  |  |  |
|   | 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.  |                         |  |  |  |  |  |
| 5)  | 5) Claim(s) is/are allowed.   |                         |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-17</u> is/are rejected.   |   |                         |  |  |  |  |  |
| 7)  | 7) Claim(s) is/are objected to.   |                         |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  Application Papers   |   |                         |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |   |                         |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |   |                         |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                         |  |  |  |  |  |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.   |   |                         |  |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |   |                         |  |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |   |                         |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |   |                         |  |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |                         |  |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |   |                         |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |   |                         |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |   |                         |  |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |                         |  |  |  |  |  |
| 14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).   |   |                         |  |  |  |  |  |
| a) The translation of the foreign language provisional application has been received.   |   |                         |  |  |  |  |  |
| 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Attachment(s)   |   |                         |  |  |  |  |  |
|   |   |                         |  |  |  |  |  |
| 2) Notic  | te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal F | r (PTO-413) Paper No(s) Patent Application (PTO-152) |  |  |  |  |

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## **DETAILED ACTION**

1. Claims 1-22 are pending.

- 2. In the response filed September 27, 2004, Applicants have elected the compound of Example 187 at pages 166 as the preferred species. Claims 1-17 are readable on the preferred species as drawn to the examined subject matter. The election is without traverse.
- 3. Claims 18-22 are withdrawn from consideration.
- 4. Rejoinder of the method claims will be addressed upon allowance of claimed subject matter.
- 5. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).
- 6. Claims 1-17 are Markush claims which are generic to the elected invention.

  These Markush claims lack unity of invention. Accordingly, the Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.
- 7. Claims 1-17 are objected on the grounds that the claims are drawn to an improper Markush group. <u>In re Harnish</u>, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group(1) share a common utility

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and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

The improper Markush groups are X and Z.

8. The examined subject matter is as follows:

A compound of formula II where G represents a carbocyclic ring, Ar represents a carbocyclic ring; X represents a 5 or 6-membered rings containing 1 or 2 nitrogen atoms; the other radical not defined herein are as defined in claim 1. The examined subject matter is allowed.

- 9. The radicals within the definition of X and Z are independent and patentable distinct. If a search is extended to other distinct species beyond that of the elected species, the following rejection is applicable.
- 10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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11. Claims 1-4, 8, and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bayer Corporation (Reference AF3, cited by applicants).

The instantly claimed compounds are disclosed. At page 75, see compounds 64-68, respectively.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,660,732. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the radical Z is optionally substituted. The radical

represented can simply be phenyl.

Response to Applicants' Remarks about the

Obviousness-Type Double Patenting Rejection

Applicants state that it is alleged that the 6,660,732 Z radical is a subgenus of the

instant Z. Applicants respectfully disagree. The instant application is a divisional case of

US 6,660,732 application serial number 09/962,709. The Office Action of 09/962,709

attached herewith as exhibit W shows on page 2, point 3 that limitation to where Z is a

ring was required. Therefore the patent's claim language, such as that in claim 1 reads:

phenyl ....each being optionally substituted with one to three ...

It is the examiner's position that:

In the application and patent, the radical Z represents phenyl.

> The radical Z is optionally substituted.

- As such, Z can present phenyl.
- 14. Applicant's arguments filed September 27, 2004 have been fully considered but they are not persuasive.
- 15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.
- 16. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Zinna Northington Davis
Primary Examiner
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Znd 3.15.2005